



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/772,502 | 02/05/2004 | David B. Rozema | Mirus.042.03 | 5669 |
| 25932 | 7590 | 06/11/2008 | | |
| MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719 | | | EXAMINER EPPS FORD, JANET L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/11/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/772,502

Applicant(s)

ROZEMA ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17, 19, 20 and 22-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17, 19, 20 and 22-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 13-17, 19-20, and 22-40 are pending for examination.

Claim Objections

3. The objection to claim 13 set forth in the prior Office Action is withdrawn in response to Applicant's amendment filed 3/07/08.

Double Patenting

4. Claims 13, 16-17 and 22-24 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-13, and 18-21 of U.S. Patent No. 7,098,032 (of record 12/18/06), for the reasons of record.
5. Applicant's arguments filed 3/07/2008 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the claims of the issued US Patent do not recite any specific polycations, however as per MPEP § 804, the previous examiner cited portions of the patent disclosure that sets forth obvious alternative preferred embodiments of the issued claims, see Example 2.
6. US Patent 7,098,032 teaches amphiphilic polymers (column 20, lines 64- column 21) and "Membrane Active" compounds (column 21, 12-31). Additionally, claims 11-13, 18-21 deal with the making an amphipathic copolymer comprising a polycation and a polyanions. Example 2 of Patent 7,098,032 uses polyvinyl ether to produce polycations, which are used in the amphiphilic copolymers of patented claim 11. Additionally, examples 5-6 of Patent 7,098,032 teach the formation of pH-labile polyampholytes

using CDM thioesters and cysteine-modified polycations, and the formation of polymer and DNA complexes in the presence of CDM modified polymers in the presence of HEPES, which are the same steps of preparation that produces the amphiphilic polymers of the instant specification (see page 17 line 22 through page 18 line 27; and page 20). Thus the polymers produced in the patent are inherently amphiphilic, in addition to being polyampholytes.

7. Moreover, in the response filed 3/07/08, Applicants argued that “instant claim 1, limited to an amphiphilic membrane active polyvinylether, would not extend the method claimed in ‘032.” This statement is improper since claim 1 was cancelled by Applicants.

8. Thus it would have been obvious to modify the claims of Patent 7,098,032 to amphiphilic polymers as the specific embodiments of Patent 7,098,032 teach the production of ampholytic, amphiphilic polymers. The double patenting rejection is maintained for reasons stated in the office action dated 12/18/06 and expanded herein.

Claim Rejections - 35 USC § 102

9. Claims 13-17, 19-20, 22 and 25-30 remain rejected and claims 31-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Meier et al (US Patent No: 6,616,946) of record 12/18/06.

10. Applicant's arguments filed 3/07/08 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the polyvinylether copolymers of Meier et al. do not possess membrane activity as the polyvinylether copolymers recited in the instant claims. In light of Applicant's lack of evidence, if the prior art describes the same polyvinyl copolymers, absent evidence to

the contrary, the ordinary skilled artisan would have a reasonable expectation that the prior art compounds would inherently possess the same characteristics as Applicant's claimed compounds.

11. Moreover, Applicants argue that the by amending the claims to recite wherein the polyvinylether polymer is a random polymer further distinguishes their invention from the teachings of Meier et al. Applicants argued that Meier et al. Contrary to Applicant's assertions, although the disclosure of Meier et al. teaches block copolymers, this disclosure does not exclude random polymerization, see for example col. 6 (Section 2. pH responsive polymers), and col. 7 (§ 5. Dual or Multi Stimuli Responsive Polymers) which describes a process of random copolymerization.

Claim Rejections - 35 USC § 103

12. Claim 23-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Meier et al (US Patent No: 6,616,946) in view of Merdan et al (Prospects for cationic polymers in gene and oligonucleotide therapy against cancer, Advanced Drug Delivery Reviews, 2002. 54:715-758) of record 12/18/06.

13. Applicant's arguments filed 3/07/08 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the amendment arguments presented in response to the 102(e) rejection over Meier et al. are sufficient to obviate the instant 103 rejection. Contrary to Applicant's assertions, as noted above, Meier et al. teach both block and random copolymerization of polyvinylethers as set forth in the instant amended claims. Therefore, Applicant's arguments are not sufficient to obviate the instant rejection.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 13-17, 19-20, and 22-40 are rejected under 35 U.S.C. 102(e) or (a) as being anticipated by Trubetskoy et al. (US 2003/0026841 A1)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US Patent Application 20030026841 teaches a process for delivery of a polyion to a cell, comprising: forming a complex of labile polyampholyte and polyion; and, delivering the complex into a cell (§ [0022]).

The complexes of the invention are disclosed as useful for both gene therapy, which includes both delivery of gene that expresses a foreign or native protein, or antisense or ribozymes to inhibit the expression of an mRNA ([0016]-[0019]).

In regards to polyampholytes of this invention, it is stated that:

[0059] *Random copolyampholytes* are polyampholytes in which the cationic and anionic monomers repeat in a random fashion. The monomers in these polyampholytes may, but need not be, polymers themselves. Cleavage of the bonds between monomers results in anions and cations or polyanions and polycations (if the monomers are polycations and polycations).

Additionally, in regards to the polymers of this invention, it is stated that:

[0151] A polymer is a molecule built up by repetitive bonding together of smaller units called monomers. In this application the term polymer includes both oligomers which have two to about 80 monomers and polymers having more than 80 monomers. The polymer can be linear, branched network, star, comb, or ladder types of polymer. The polymer can be a homopolymer in which a single monomer is used or can be copolymer in which two or more monomers are used. *Types of copolymers include alternating, random, block and graft.*

Moreover, this reference teaches amphiphilic polymers (§ [0140]) and "Membrane Active" compounds (see § [0142]). Example 2 uses polyvinyl ether to produce polycations, which are used in the amphiphilic copolymers of patented claim 11.

Additionally, examples 5-6 (pages 25-28) teach the formation of pH-labile polyampholytes using CDM thioesters and cysteine-modified polycations, and the formation of polymer and DNA complexes in the presence of CDM modified polymers in the presence of HEPES, which are the same steps of preparation that produces the

amphiphilic polymers of the instant specification (see page 17 line 22 through page 18 line 27; and page 20).

Thus the polyvinylether polymers produced in this reference are inherently amphiphilic, in addition to being polyampholytes, moreover random copolymers are also encompassed by this reference.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

/JLE/